

REMARKS

Entry of the foregoing amendments and favorable reconsideration of the subject application, pursuant to and consistent with 37 C.F.R. § 1.112, and in light of the remarks which follow, are respectfully requested. This amendment is in response to the non-final Official Action mailed on April 1, 2009. Claims 61 and 91 have been amended. Support for the amendments is found on page 12, 11.23-30 of the application as filed. No new matter has been added by way of this amendment.

The Examiner has rejected claims 61, 62, 70-72, 77, 78, 82, 84, 85, and 91 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particular point out and distinctly claim the subject matter which applicant regards as the invention. *Office Action*, pages 2-3. Specifically, the Examiner has rejected claims 61 and 91 as "vague" because it is unclear whether the phrase "'said skin lipids are selected from the group consisting of cholesterol, cholesterol sulfate, ceramide [1] and ceramide 2' refers to the skin lipids 'of a subject having a quantity of skin lipids' or to skin lipids that increase after the administration of the claim-designated ingredients." *Id.* at 3. Applicants have amended claims 61 and 91 to clarify that the skin lipids that increase after administration are selected from the group consisting of cholesterol, ceramide 1, and ceramide 2. Accordingly, this rejection should be withdrawn.

The Examiner has also objected to claim 61 because it contains the abbreviation "UV". *Id.* at 3-4. Applicants have amended the claim to recite "ultraviolet (UV)" per the Examiner's recommendation. Accordingly, this objection should be withdrawn.

The Examiner has also rejected claims 61, 62, 70-72, 77, 78, 82, 84, 85, and 91 under 35 U.S.C. §103(a) as being

unpatentable over *Sekimoto* (JP57131716) in view of *Milkova* (Nahrung (1977); 21(1): 1-6); *Alonso* (J. Am. Oil Chemist's Society (1997); 74(2): 131-135); and *Brun* (GB2066071). *Id.* at 4-9. Applicants respectfully traverse this rejection.

Applicants submit that cited references, alone or in combination, do not teach all of the elements of the claimed invention. *Sekimoto* describes a preparation comprised of sitosterol or a sitosterol-containing vegetable oil. *Sekimoto* discloses that this preparation is used to prevent drying and keratinization of plantar skin (e.g. callused skin on the sole of a foot). *Sekimoto*, p.1. Moreover, the reference discloses that "GLC analysis of the fluid secreted from the sole of a foot showed that it contained cholesterol, sitosterol, and triterpene alcohols." *Id.* Only the content of sitosterol in this sample was found to be higher than that normally found in blood. *Id.* *Sekimoto* does not, however, disclose that administration of the preparation increases the quantities of cholesterol in the skin, let alone other skin lipids including ceramide 1 and ceramide 2 as in the claimed invention. Moreover, *Sekimoto* is limited merely to treating plantar skin, and hence is directed to a completely different problem than that of the claimed invention. There is absolutely no disclosure that the preparation may be applied to treat skin conditions including atopic dermatitis, sensitive skin, irritated skin, and reactive skin as in the claimed invention.

Nor do any of the secondary references cure these deficiencies. *Milkova* and *Alonso* are merely directed to the isolation and structural elucidation of sunflower based materials. Specifically, *Milkova* is directed to the isolation of certain sterols by preparative TLC. *Milkova*, p.1. Similarly, *Alonso* is directed to "the application of a GC procedure for rapid analysis of the total sterol fraction of vegetable oils, milk, fat, or mixtures [thereof], to detect any

admixture of sunflower or olive oil and any addition of vegetable oils to milk fat." *Alonso, Abstract*. Clearly, these references do not contemplate the biological properties of sterols or their potential application to treat skin conditions such as atopic dermatitis, sensitive skin, irritated skin, and/or reactive skin as in the claimed invention. Nor does either reference teach that administration of an oil or unsaponifiable material increases the concentration of any skin lipid, let alone cholesterol or ceramides as in the claimed invention.

Finally, *Brun* discloses a cosmetic oil composition for use in cosmetics comprising a mixture of jojoba oil, sunflower seed oil, and at least one unsaponifiable fraction of a vegetable oil (e.g. soya, avocado, maize or sunflower oil). *Brun*, col.2 ll.87-92. *Brun* discloses that these compositions maintain the water content of the skin by preventing water from evaporating and, thus are useful for improving the appearance of senile, dry or rough skin. *Id.* at col.2. ll.71-75. Like *Sekimoto*, *Milkova*, and *Alonso*, *Brun* does not disclose that administration of a composition comprising a plant oil increases the quantity of cholesterol, ceramide 1, or ceramide 2, let alone is useful in treating atopic dermatitis, sensitive skin, irritated skin, or reactive skin as in the claimed invention. Accordingly, there is no disclosure in the cited art that distillates or unsaponifiable materials from sunflower oil activate neosynthesis of ceramides or cholesterol, increasing their quantities, for treatment of the claimed skin conditions. Therefore, a *prima facie* case of obviousness has not been established and, as a result, the rejection should be withdrawn.

Applicants have found that the claimed invention induces neosynthesis of ceramides and cholesterol. Indeed, Applicants have conducted experiments which show, surprisingly, that the claimed invention significantly increases neosynthesis

of skin lipids when compared to controls. *Application*, page 24. In fact, the neosynthesis of ceramides is higher after treatment with sunflower distillate/unsaponifiable material than after treatment with epidermal growth factor or with lactic acid, which are both known to stimulate synthesis of ceramides in the skin. *Id.* Applicants have also conducted clinical studies to evaluate the effect of a cosmetic composition comprising the designated ingredients. *Id.* at page 33. The results of these studies indicate a "statistically significant increase in the level of surface skin lipids" relative to controls. *Id.* at pages 36-37. As explained above, none of the cited references show increases in the quantities of cholesterol or ceramides or treatment of the skin conditions of the claimed invention.


As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By   
Thomas M. Finetti  
Registration No.: 61,881  
LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK, LLP  
600 South Avenue West  
Westfield, New Jersey 07090  
(908) 654-5000  
Attorney for Applicant